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(54) Dual site pacing system with automatic pulse output adjustment

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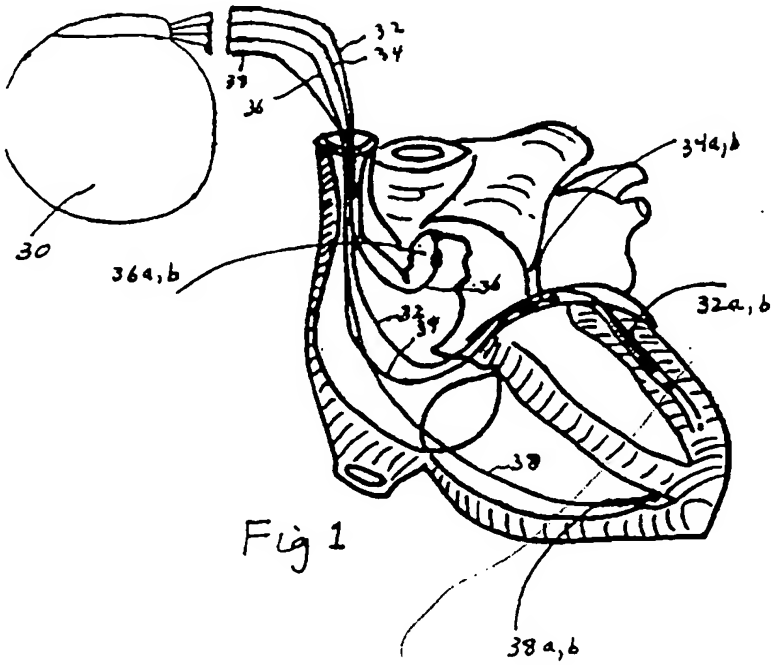

Fig 1

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[0007] In prior art single chamber and dual chamber pacing systems, a great deal of effort has been expended to develop pacemakers having the capability of automatically testing the stimulation threshold. i.e., providing an "auto-capture" detection function, and resetting the pacing pulse energy to exceed the threshold by the safety margin without the need for clinical or patient intervention. A wide variety of approaches have been taken in the pacemaker art as reflected by the patent literature. See, for example, U.S. Patents 5,324,310; 5,320,643; 5,165,404; 5,165,405; 5,172,690; 5,222,493; and 5,285,780. The capture detection threshold tracking approaches in the prior art have taken a variety of forms, and typically attempt to overcome the difficulty in detecting the evoked cardiac response wave shape from the pacing electrodes employed to deliver the pacing pulse. High stimulation energy pacing pulses and the ensuing after potentials and electrode-tissue polarization artifacts mask the evoked response, and also saturate the sense amplifiers coupled to the electrodes, until they dissipate. By the time that the sense amplifier is no longer "blinded," the evoked response, if any, has typically passed the electrodes. As a consequence, most of the prior art approaches rely on additional components and circuitry, and more complex logic, which consume energy, add to the bulk and cost of the system, and also raise reliability issues. This situation is, of course, worsened in the case of dual site pacing systems. There is thus an aggravated need in the area of dual site pacemakers to provide a reliable technique for determining whenever there is loss of capture (LOC) in either chamber, without compounding the circuitry and logic complexity of the pacemaker.

[0008] It is an object of the invention to provide an efficient and reliable means of determining occurrences of loss of capture in a dual site pacing system, e.g., for a bi-ventricular pacing system, which can determine any occurrence of loss of capture in either the left or right ventricle; and to adjust pulse output accordingly to a safe level above threshold. The determination should preferably be made using circuitry and logic capability already in place, to optimize cost and reduce power consumption, while ensuring reliable detection.

[0009] The above object is accomplished in this invention by providing a cardiac pacing system with biventricular pacing of a patient, comprising:

pulse means for generating a pair of concurrent pacing pulses;

lead means for delivering one of said concurrent pacing pulses to the patient's right ventricle and one of said concurrent pacing pulses to the patient's left ventricle, said lead means further having electrode means for sensing excitation signals in each of said ventricles;

refractory means for timing out a refractory interval following each delivery of a said pair of concurrent pacing pulses, and sensing means electrically connected to said lead means for determining when a said excitation signal has been sensed in at least one ventricle by said electrode means during a said refractory interval; and

LOC means for indicating loss of capture in at least one of said ventricles in response to sensing one or at least ventricular excitation signal during said refractory interval.

[0010] For a bi-ventricular pacing system, where pacing pulses are delivered substantially concurrently to both ventricles, when capture is achieved in both ventricles, no intrinsic depolarization signals can be sensed during the following refractory period. However, where the output level of one of the pacing pulses is insufficient to capture the ventricle, but capture is achieved in the other ventricle, a delayed depolarization pattern results in a "sense" in the ventricle where there was loss of capture. For example, for a heart with LBBB, failure to capture in the left ventricle results in a delayed depolarization in the left ventricle on the order of up to 120-150 ms. This delayed depolarization transferred from the right ventricle comes after the blanking period but during the left ventricular refractory period. Sensing of such a delayed signal during the refractory period (here referred to as a VR) is thus an indication of loss of capture (LOC).

[0011] In accordance with the above, there is provided a dual site pacing system with the capability of automatically detecting when there is LOC at one of the sites, either ventricular or atrial. Following each delivered pair of pacing pulses to the dual sites, the pacemaker times out an appropriate blanking interval, and then times out a refractory period to coincide with the heart chamber's normal period of refractoriness following a contraction. During the refractory interval, or refractory period (RP), the pacemaker looks to see if an excitation signal is sensed. If yes, this means that a chamber was not captured, and the excitation from the other chamber (which was captured by a delivered pulse) had been conducted to the non-captured chamber. Accordingly, a sense during the RP, herein called a VR, is used to logically indicate LOC. The pacemaker responds by automatically increasing PO of the delivered pulses. The pacemaker may have one sense channel for the two dual site chambers, and increase PO for both pulses upon detection of a VR; or may have dual channels, and increase PO only for the chamber from which the VR was detected.

[0012] According to another aspect of the invention, there is provided a dual site cardiac pacing system, providing for delivery of substantially concurrent pacing pulses to dual sites in a patient's heart, said system having a pacemaker and leads connected to said pacemaker for delivering pacing pulses to said sites and for obtaining cardiac senses from each of said sites, said pacemaker comprising:

pulse generator means for cyclically generating

VRP through a range, e.g., from 150 to 500 ms, in steps of 10 ms. However, since IVCD rarely is greater than 280 ms, VRP would generally be programmed through a range from about 150 to 300 ms in the practice of this invention. The LOC detection algorithm recognizes LOC after a pattern of VRs, e.g., one or more VRs, but does not react to VSs, which occur outside the VRP window.

[0022] Referring now to Figure 3, there is shown a series of curves illustrating delivery of progressively lower PO pacing pulses to each ventricle, resulting in (DSC) dual site capture (dual ventricular capture), then (SSC) single site capture (single ventricular capture), and finally complete (LOC) loss of capture (capture in neither ventricle). The upper curve shows a surface ECG, corresponding to continued decrease in PO of the dual pulses occurring simultaneously as pulse pairs. The marker channel indicates delivery of dual pulses, indicated as VP; it indicates sensed signals during the refractory interval, indicated as VR; and it shows the blanking period, typically 8-16 ms following the VP, followed by the refractory interval, indicated as RP. The bottom curve represents the intracardiac signal as obtained by the pacemaker. The patient represented by Figure 3 has an LBBB, as well as an Intra-Atrial Conduction Defect (IACD), resulting in slow P wave propagation from RA to LA. The first two pulse pairs had sufficient PO to obtain dual site capture. Thus, for these two cycles, the QRS and T wave portions can be seen following the delivery of the VP. However, upon delivery of the third pair of pulses, one ventricle, in this case left ventricle, is not captured. The surface ECG shows an extended signal manifested as an increase in QRS duration, the effect of LBBB, which also can be seen in the bottom curve (EGM signal). As shown on the marker channel, a VR is obtained. After six consecutive single site captures, the PO is reduced to the point where there is no capture in either ventricle. As can be seen, after the first cycle of no capture, no signal is sensed. After the second no capture pulse pair, an intrinsic signal is seen, which apparently is blanked. After the third such no capture pulse pair, the intrinsic signal is sensed within the RP, as indicated by the VR on the marker channel, confirming LOC.

[0023] Examination of Figure 3 indicates that it is extremely unlikely that the pacemaker would have a no pacing cycle, where neither chamber was captured. Fluctuations of acute and chronic thresholds at each site are independent of each other, such that the thresholds of the two sites will never be exactly the same. A change in either threshold with time would initially result in one ventricle or the other (or one atrium or the other) experiencing LOC, which would result in a VR and automatic increase in PO. The invention capitalizes on the observation that when capture is lost at one of the dual pacing sites, the conduction delay results in an intrinsic signal detection after blanking but before the end of the refractory period enabling an automatic increase of the pacing stimulus PO, e.g., increase of either amplitude or width, to regain capture at both sites. Of course, in a normal heart the intrinsic conduction delay from RV to LV would be +50-60 ms, and would be within the absolute blanking period, but bi-ventricular pacing would not be indicated for such a patient.

[0024] Referring now to Figure 4A, there is shown a flow diagram of the basic steps of monitoring capture or no capture. At 55, the pacemaker delivers the bi-ventricular pace pulses, followed by the timing out of a blanking period at 56. Following this, the pacemaker times out the refractory period (VRP), as indicated at block 57, and at 58 waits to see if there is a VR, i.e., a sense of an intrinsic signal during the VRP. If not, dual capture is presumed, and the routine exits and awaits the next cycle. If yes, at 60 the pacemaker automatically increments the PO, in order to maintain PO safely above threshold. The amount of increase is a design variable, and can be programmed accordingly. Alternatively, the routine may require detection of X consecutive VRs before implementing an increase in PO, e.g., 2-5 VRs; or other patterns of detected VRs.

[0025] Referring to Figure 4B, there is shown a variation of Figure 4A, wherein the pacemaker can conduct a threshold test. A test may be automatically initiated, e.g., every N days, or may be initiated by external programming. If the test is called for, as indicated at 52, then at 54 the pacemaker automatically decreases the PO by ΔP. Following this, steps 55-58 are carried out. At 58, if no VR is sensed, this means that there is still dual site capture, and the routine branches to block 59 to determine whether a test is in progress. If yes, the routine returns to 54, and again decreases the PO; if no, the routine exits. This continues until a VR is found, and following this PO is increased as indicated at block 60.

[0026] It is to be understood that the flow diagrams 4A, 4B apply equally to a pacemaker with a single sensing channel, or a pacemaker with separate sensing channels. Thus, for a pacemaker with a single sensing channel, if a VR is sensed, then the increase of PO applies to each pulse of the dual site pulse pair. If dual sensing channels are utilized, the increase of PO applies only to the pulses outputted to the heart chamber where failure of capture had been indicated by the VR.

[0027] It is thus seen that there is a very simple yet elegant procedure provided for reliably sensing loss of capture in dual site pacing, for patients where the conduction dysfunction causes either an interventricular delay or interatrial delay in excess of the blanking period.

Claims

1. A cardiac pacing system with bi-ventricular pacing of a patient, comprising:

   pulse means (30) for generating a pair of concurrent pacing pulses;
   lead means (32, 34, 36, 38) for delivering one

the output level of the pulses delivered to both of said dual sites.

14. The pacing system as described in claim 12, wherein said sensing means comprises first means for sensing when a ventricular sense occurs in the left ventricle during said refractory interval, and second means for sensing when a ventricular sense occurs in the right ventricle during said refractory interval, and said LOC means comprises VR means for indicating the ventricle in which a ventricular sense has occurred during the refractory interval (VR).

15. The pacing system as described in claim 14, wherein said response means comprises means for increasing the output level of the pulses delivered to the ventricle where a VR has been indicated.

16. The pacing system as described in any of claims 10 to 15, wherein said sensing means comprises means for determining a pattern of cardiac senses during the refractory interval, and said LOC means indicates loss of capture when a said pattern is determined.

17. The pacing system as described in any of claims 10 to 15, comprising programming means for programming said refractory interval to a value in the range of about 150-300 ms.

18. The pacing system as described in claim 10, adapted for delivery of substantially concurrent pacing pulses to dual sites in a patient's heart, said patient's heart being characterized by an IVCD of up to 300 ms; wherein

said refractory means times out a programmable refractory interval as set to a value greater than said patient IVCD following each generation of said concurrent pulses; and said pacemaker further comprising
response means for responding to an indicated loss of capture by increasing the output level of at least one of said concurrent pulses in response to an indicated LOC.

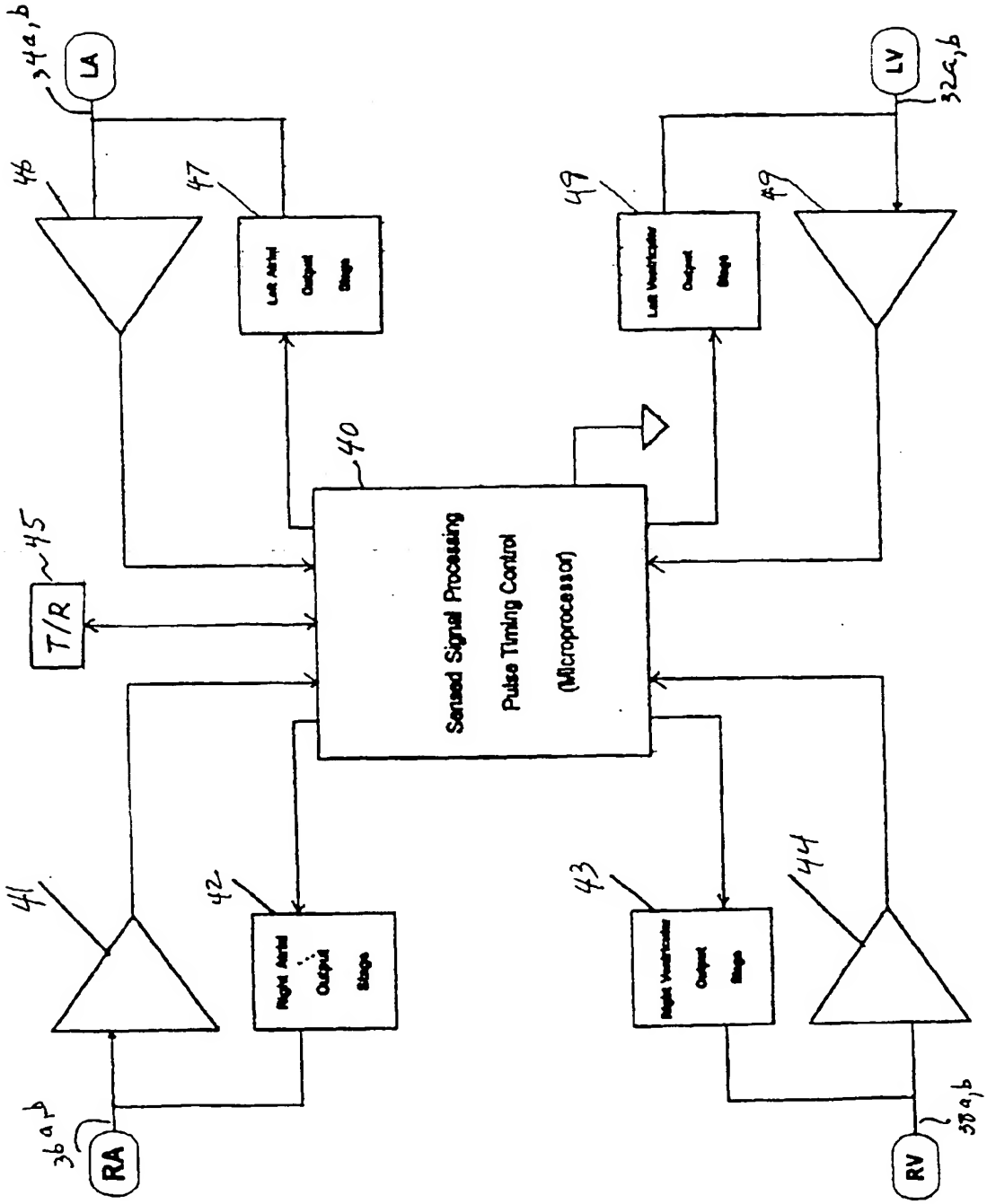

Fig 2

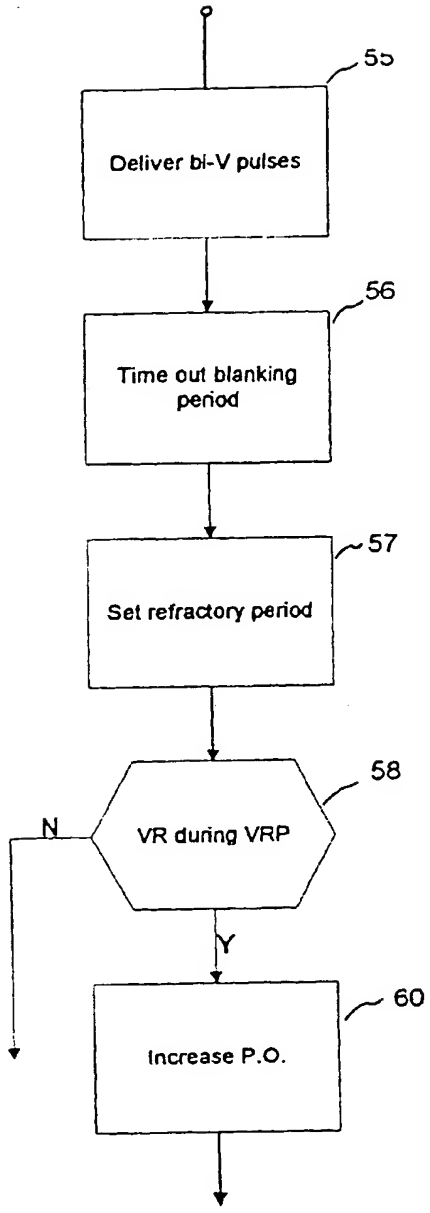

Fig. 4A

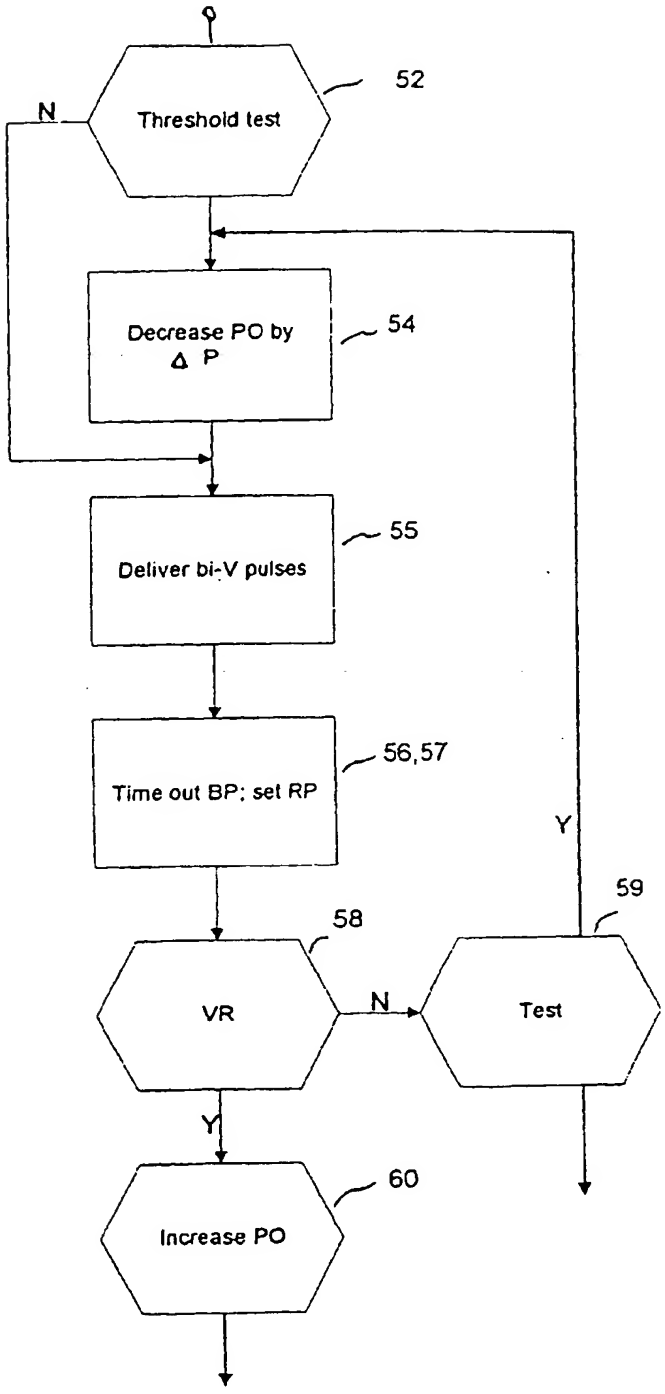

Fig. 4B

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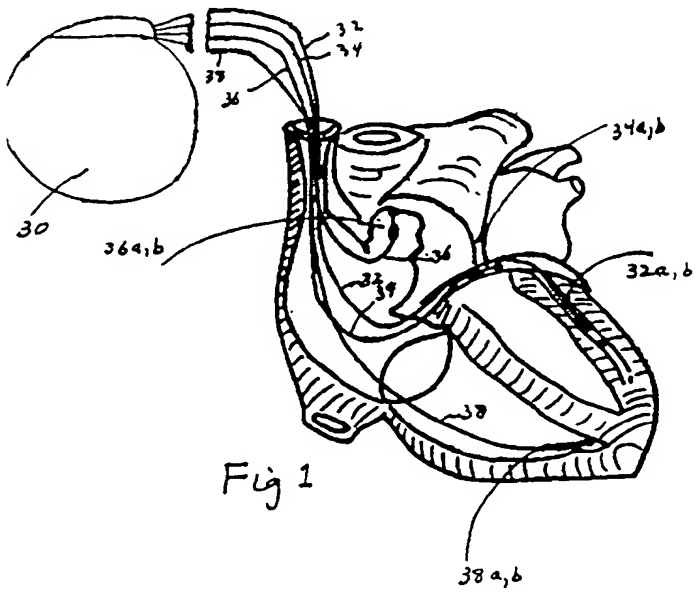

Fig 1

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